REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-14 are still pending in this application. The amendment to claim 14 should be entered as it reduces the number of issues for Appeal and has been made to be consistent with the Examiner's interpretation of the claim in the previous Office Action. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE OBJECTIONS TO THE CLAIMS HAVE BEEN OVERCOME

The objection to claim 14 has been overcome as the claim has been amended in accordance with the Examiner's interpretation in the previous Office Action.

III. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

Claims 1-14 were rejected as allegedly being obvious Rupprecht et al. (US 2002-0142036 -"Rupprecht") in view of Levin (US 6,432,986 -"Levin"). The applicants request reconsideration of this rejection for the following reasons. (As method claims 10-12 include the use of the dosage forms of claim 1, and the use of Levin appears primarily directed to the method of use claims, claims 10-12 would stand or fall with the dosage form claims).

The applicants maintain their position from the previous office action, but would like to address the points raised in the "Response to Arguments" section of the Office Action.

1) "Rupprecht et al. clearly teaches a range for the ratio of polymer to crosslinker (4:1 to 1:2) that overlaps with the claimed range (2:1 to 5:1)

This aspect of the applicants' arguments was misinterpreted in the Office Action and reflects a failure to consider the applicants' invention as a whole, i.e. the applicants invention is

not each of the claimed elements in isolation, but each of the elements in combination. The combination of Rupprecht and Levin does not teach or suggest the simultaneous combination of a dosage form for nasal use which at least one lidocaine containing layer based on crosslinked hydrophilic polymers from 30% by weight to 60% by weight of lidocaine, based on the total amount of crosslinked hydrophilic polymers, wherein the dosage form has a tear strength of at least 40 N and the hydrophilic polymer of the active ingredient-containing layer has been crosslinked in situ and the ratio of hydrophilic polymers to crosslinker is from 2:1 to 5:1 by weight.

The fact that Rupprecht may overlap in one aspect of the applicants' invention does not indicate that other features of the applicants' dosage form has been achieved, i.e. the amount of lidocaine and a tear strength of at least 40 N.

2) **"…the examiner asserts that the ratio of polymer to crosslinker is the condition required to control the tear strength and as already laid out above, the ratio taught by Rupprecht et al. overlaps with the instantly claimed range"**

This assertion is in error on two counts.

First, it is well known that obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993), *see also MPEP 2141.02*.

Second, the tear strength is not only a feature of the ratio of hydrophilic polymers to crosslinker, but also of the active substance selected; in the present invention, lidocaine. As the Examiner noted in the Office Action, Rupprecht is silent on tear strength and correspondingly is silent on tear strength for a dosage form with lidocaine as an active ingredient.

3) **"Rupprecht et al. specifically teaches lidocaine as a suitable active agent in the composition, hence one of ordinary skill in the art would be motivated [to] use it as an active agent"**

This is a mischaracterization of the teaching of Rupprecht as this reference is far from being specific for any active ingredient save for prednisolone. Paragraphs [0028] – [0045] of Rupprecht refer to the active ingredients which are usable "in principle" and is reproduced below (lidocaine is in bold, italics and underlining):

"[0028] In principle, there is no restriction on the active substances contained in the active substance-containing layer. Preferably however, the active substances are aromatic principles, aroma substances, diagnostic agents, plant protection agents, pharmaceutical active substances, vitamins, nutrients and/or fertilizers. Suitable pharmaceutical active substances include analgesics, antiallergic agents, antibiotics, antiemetics, antiseptics, antihistamines, antihypertensive agents, appetite suppressants, cardiac agents, chemotherapeutics, enzyme preparations, hormones, immunomodulators, local anaesthetics, psychopharmaceuticals, spasmolytics, virustatics, vitamins and cytostatics.
[0029] Suitable active substances also include diamorphine, alflentanil, sufentanyl, pentazocin, buprenorphin, nefopam, flupirtin, tramadol, oxycodon, metamizol, propyphenanzone, phenazone, nifenazone, phenylbutazone, oxyphenbutazone, mofebutazone, diflunisal, meptazinol, methadone, pethidine, meloxicam, fenbufen, mefenamic acid, tenoxicam, azapropazon, piritramide, tramadol, amantadine, benzotropine, procyclidine, moclobemide, tranylcypromide, maprotilin, doxepine, opipramol, desipramine, imipramine, fluroxamine, paroxetin, trazodone, viloxazine, fluphenazine, perphenazine, promethazine, thioridazine, triflupromazine, prothipendyl, tiotixen, chlorprothixen, pipamperone, pimozide, fenethyllin, trifluoperazine, thioridazine, oxazepam, alprazolam, clobazam, piracetam, melfalan, cyclophosphamide, trofosfamide, chlorambucil, lomustin, busilfan, prednimustin, mercaptopurine, thioguanine, hydroxycarbamide, altretamine, procarbazine, lisuride, methysergide, pizotifen, roxatidine, pirenzipine, proglumide, bromopride, pheniramine, dimethindene, tritoqualine, loratadine, doxylamine, mequitazine, dexchlorpheniramine, triprolidine, oxatomide, moxonidine, doxazosine, urapidil, dihydralazine, deserpidine, alprenolol, bupranolol, penbutolol, esmolol, ciliprolol, metipranolol, nadolol, quinapril, fosinopril, cilazapril, democlocycline, lymecycline, oxytetracycline, sulfamethopyrazine, aerosoxacine, becampicillin, piperacillin, pivampicillin, cloxacillin, flucloxacillin, metronidazol, clindamycin, cefaclor, cefpodoxime, cephalexin, cefradin, pirbuterol, orciprenalin, clenbuterol, procaterol, choline theophyllinate, theophylline, ethylenediamine, ketofen, viquidil, procainamide, mexiletin, tocainid, ipratropium, tobutamide, gliquidon, gliboruride, tolazamide, acarbose and pharmaceutically active salts or esters of the aforementioned active substances as well as combinations of two or more of these active substances or their salts or esters.
[0030] Other suitable active substances include, for example, acebutolol, acetylcysteine, acetylsalicylic acid, aciclovir, albrazolam, alfacalcidol, allantoin, allopurinol, ambroxiol, amikacin, amiloride, aminoacetic acid, amiodaron, amitriptylin, amlodipin, amoxicillin, ampicillin, ascorbic acid, aspartam, astemizole, atenolol, beclometason, benserazide, benzalkonium hydrochloride, benzocaine, benzoic acid, betametasone, bezafibrate, biotin, biperidene, bisoprolol, bromacepam, bromhexine, bromocriptine, budesonide, bufexamac, buflomedil, busprione, caffeine, camphor, captopril, carbamacipine, carbidopa, carboplatin, cefaclor, cefalexin, cefadroxil, cefazolin, cefixime, cefotaxim, ceftazidin, ceftriaxon, cefuroxim, celedilin, chloramphenicol, chlorhexidine,

chlorpheniramine, chlortalidone, choline, ciclosporin, cilastatin, cimetidine, ciprofloxacin, cisaprid, cisplatin, clarithromycin, clavulanic acid, clomibramin, clonazepam, clonidine, clotrimazole, codeine, cholestyramine, cromoglicinic acid, cyanocobalamin, cyproteron, desogetrel, dexamethason, dexpanthenol, dexthromethorphan, dextropropoxiphen, diazepam, diclofenac, digoxin, dihydrocodeine, dihydroergotamine, dihydroergototoxin, diltiazem, diphenhydramine, dipyridamol, dipyrone, disopyramide, domperidon, dopamine, doxcycline, enalapril, ephedrine, epinephrine, ergocalciferol, ergotamine, erythromycin, estradiol, ethinylestradinol, etoposid, famotidin, felodipin, fenofibrate, fenoterol, fentanyl, flavin mononucleotide, fluconazol, flunarizin, fluorouracil, fluoxetin, flurbiprofen, furosemide, gallopamil, gemfibrozil, gentaminicin, ginkgo biloba, glibenclamide, glipizid, glozapine, glycyrrhiza glabra, griseofulvin, guaifenesin, haloperidol, heparin, hyaluronic acid, hydrochlorothiazide, hydrocodon, hydrocortisone, hydromorphone, ibratropium hydroxide, ibuprofen, imipenem, indomethacin, iohexol, iopamidol, isosorbid dinitrate, isosorbid mononitrate, isotretionin, ketotifen, ketoconazol, ketoprofen, ketorolac, labatalon, lactulose, lecithin, levocarnitin, levodopa, levoglutamide, levonorgestrel, levothyroxin, ***lidocaine***, lipase, lipramin, lisinopril, loperamid, lorazepam, lovastatin, medroxyprogesterone, menthol, methotrexate, methyldopa, methylprednisolone, metoclopramide, metoprolol, miconazol, midazolam, minocyclin, monoxidil, misoprostol, morphine, multivitamins and minerals, N-methylephedrine, naftidrofuril, naproxen, neomycin, nicardipin, nicergolin, nicotinamide, nicotine, nicotinic acid, nifedipin, nimodipin, nitrazepam, nitrendipin, nizatidin, norethisteron, norfloxacin, norgestrel, nortriptylin, nystatin, ofloxacin, omeprazol, ondansetron, pancreatin, panthenol, pantothenic acid, paracetamol, penicillin G, penicillin V, phenobarbital, phenoxifyllin, phenoxymethylpenicillin, phenylephrin, phenylpropanolamine, phenytoin piroxicam, polymxyxin B, povidine-iodine, pravastatin, prazepam, prazosin, prednisolone, prednisone, propafenone, propranolol, proxyphyllin, pseudoephedrine, pyridoxine, chinidin, ramipril, ranitidin, reserpine, retinol, riboflavin, rifampicin, rutosid, saccharin, salbutamol, salcatonin, salicylic acid, simvastatin, somatropin, sotalol, sprironolactone, sucralfate, sulbactam, sulfamethoxazole, sulfasalazin, sulpirid, tamoxifen, tegafur, teprenon, terazosin, terbutalin, terfenadin, tetracycline, theophylline, thiamine, ticlopidin, timolol, tranexamic acid, tretinoin, triamcinolone acetonide, triamteren, trimethoprim, troxerutin, uracil, valproic acid, vancomycin, verapamil, vitamin E, zidovudine.

[0031] Additional examples of suitable active substances that may be released from the multi-layer film according to the invention include proclorperazine edisylate, iron II sulfate, aminocaproic acid, potassium chloride, mecamylamine hydrochloride, procainamide hydrochloride, amphetamine sulfate, benzphetamine hydrochloride, isoporterenol sulfate, methamphetamine hydrochloride, phenmetrazine hydrochloride, bethanechol chloride, methacholine chloride, pilocarpine hydrochloride, atropine sulfate, methascopolamine bromide, isopropamide iodide, tridihexethyl chloride, phenformine hydrochloride, methyl phenidate hydrochloride, oxprenolol hydrochloride, metroprolol tartrate,

cimetidine hydrochloride, diphenidol, meclizine hydrochloride, proclorperazine maleate, phenoxybenzamine, thiethylperazine maleate, anisindone, diphenadione, erythritol tetranitrate, dizoxin, isofurophate, acetazolamide, methazolamide, bendroflumethiazide, chlorpropamide, tolazamide, chlormadinone acetate, phenaglycodol, aluminium aspirin, methotrexate, acetylsulfioxazole, progestins, estrogen steroids, progestatin steroids, corticosteroids, 17-[beta]-oestradiol, ethinyloestradiol-3-methyl ester, hydrocorticosterone acetate, methyltesterone, 17-[alpha]-hydroxyprogesterone acetate, 19-norprogesterone, norethindrone, progesterone, norgesterone, norethynodrel, etc.

[0032] Examples of still more active substances that may be released with the aid of the multi-layer film of the invention include fenoprofen, sulindac, indoprofen, nitroglycerin, timolol, alprenolol, imipramine, chlorpromazine, dihydroxyphenylalanine, pivaloxyloxyethyl ester of [alpha]-methyldopa hydrochloride, calcium gluconate, iron II lactate, vincamin, phenoxybenzamine, blockers, etc. The active substances are known from "Pharmaceutical Sciences" by Reminston, 14thEdition, 1979, Mack Publishing Co., Easton, Pa.; "The Drug, The Nurse, The Patient, Including Current Drug Handbook", 1974-1976, by Falconer et al., Saunder Co., Philadelphia, Pa., and "Medical Chemistry", 3<rd >Edition, Vols. 1 and 2, by Burger, Wiley Interscience, New York.

[0033] Representative medicaments that may be administered to warm-blooded animals, for example ruminants, with the aid of the release system according to the invention include, inter alia, anthelmintics such as mebendazol, levamisol, albendazol, cambendazol, fenbendazol, parbendazol, oxfendazol, oxybendazol, thiabendazol, tichlorfon, praziquantil, morantel and pirantel, etc.; antiparasitic agents such as avermectine and ivermectin, as are disclosed in U.S. Pat. Nos. 4,199,569 and 4,389,397 (Merck) and in "Science", Vol. 221, pp. 823-828, 1983, where these ivermectin antiparasitic agents are said to be suitable to assist in controlling worms such as roundworms (maw-worms), lung worms etc. that commonly occur in mammals, and also that ivermectin is suitable for treating infestation by insects such as maggots, lice, mite mange, etc.; antimicrobial agents such as chlortetracycline, oxytetracycline, tetracycline, gentamicin, streptomycin, dihydrostreptomycin, bacitracin, erythromycin, ampicillins, penicillins, cephalosporins, etc.; sulfur-containing medicaments (sulfa drugs) such as sulfamethazine, sulfathiazole, etc.; growth stimulators such as Monesin(R) sodium and Elfazepam(R); de-fleaing agents such as dexamethazone and flumethazone; agents and ionophores influencing digestion in stomachs of ruminants, such as lasalocid, virginamycin, salinomycin and ronnel; minerals such as copper oxide, cobalt sulfate, potassium iodate, zinc oxide, manganese sulfate, zinc sulfate, selenium, sodium selenite, beneficial mineral salts, etc.; antiswelling agents such as organic polysiloxanes; hormone growth additives such as stilboestrol; vitamins such as vitamins A and D with 500,000:100,000 IU/f, vitamin E with 500,000 IU/f, etc.; anti-enteritis agents such as furazolidone, growth factors, nutrient additives such as lysine monohydrochloride, methionine, magnesium carbonate, etc.; [beta]-agonists, elenbuterol, etc. and chemical labelling substances such as chromium oxide, and salts of ytterbium and erbium.

[0034] Suitable locally-acting pharmaceutically active substances also include fungicides such as amphotericin B, antibiotics such as penicillins, cephalosporins, erythromycin, tetracycline, aminoglucosides, antiviral compounds such as acyclovir, idoxuridin, respiratory improvers such as chlorophyll, compounds inhibiting tissue growth, anticaries compounds such as metal fluorides, in particular sodium monofluorophosphate, tin fluoride, aminofluoride, painkillers such as methyl salicylate, local anaesthetics such as benzocaine, oral antiseptics such as chlorhexidine and its salts, hexylresorcinol, dequalinium chloride, cetylpyridine chloride, anti-inflammatory agents, hormones such as oestriol, anti-plaque compounds such as chlorhexidine and its salts, octenidine, or mixtures of thymol, menthol, methyl salicylate, eucalyptol, buffer compounds such as calcium phosphate, calcium carbonate, sodium bicarbonate, sodium and calcium hydroxide, as well as desensitisers for teeth, such as for example calcium nitrate.
[0035] Suitable active substances furthermore include disinfectants such as chlorine compounds, in particular calcium hypochlorite, an insecticide, pesticide, herbicide, fungicide or growth promoter, or fertilisers such as for example nitrogen-containing compounds, in particular urea, urea/formaldehyde compounds, calcium nitrate, calcium sulfate, calcium chloride, ammonium nitrate, ammonium sulfate, monoammonium phosphate, dibasic ammonium phosphate, ammoniumphosphoric acid compounds, trace elements for foodstuffs, such as iron, zinc, manganese, copper, boron, molybdenum or mixtures thereof.
[0036] Active substances that are suitable for the production of the transdermal systems according to the invention also include steroid hormones such as:
[0037] Gestagen-active steroid hormones, such as for example 13-ethyl-17[beta]-hydroxy-18,19-dinor-17[alpha]-pregn-4-en-20yl-3-one, 13-ethyl-17[beta]-hydroxy-18,19,-dinor-17[alpha]-pregna-4,15-dien-20yn-3-one (=Gestoden), 13-ethyl-17[beta]-hydroxy-11-methylene-18,19-dinor1-17[alpha]-pregn-4-en-20yne or 13-ethyl-11-methylene-17[beta]-hydroxy-18,19,-dinor-17[alpha]-pregn-4-en-3-one (3-keto-desogestrel), estrogen-active steroid hormones, e.g. 3-hydroxy-1,3,5-(10)-estratriene-17-one (=Estron), 1,3,5(10)-estratriene-3,17[beta]-diol or 1,9-nor-17[alpha]-pregna-1,3,5(10)-trien-20yn-3,17[beta]-diol, 17[beta]-hydroxy-19-nor-17[alpha]-pregn-4en-20yn-3-one, 14[alpha], 17[alpha]-ethano-1,3,5(10)-estratriene-3,17[beta]-diol (=Cyclodiol) and 14[beta], 17[alpha]-ethano-1,3,5(10)-estratriene-3,16[alpha],17[beta]-triol (=Cyclotriol) and combinations of these gestagens and estrogens.
[0038] Androgen-active steroid hormones such as 17[beta]-hydroxy-4-androsten-3-one (=testosterone) and its esters, or 17[beta]-hydroxy-1[alpha]-methyl-5[alpha]-androsten-3-one (=mesterolone).
[0039] Anti-androgen active steroid hormones such as 17[alpha]-acetoxy-6-chloro-1[beta],2[beta]-dihydro-3H-cyclopropa[1,2]-pregna-1,4,6-triene-3,20-dione.
[0040] Corticoids such as 11[beta],17[alpha],21-trihydroxy-4-pregnene-3,20-dione, 11[beta],17[alpha],21-trihydroxy-1,4-pregnadiene-3,20-dione, 11[beta],17[alpha],21-trihydroxy-6[alpha]-methyl-1,4-pregnatriene-3,20-dione, and 6[alpha]-fluoro-11[beta],21-dihydroxy-16[alpha]-methyl-1,4-pregnadiene-

3,20-dione (=diflucortolone) and their esters.
[0041] Suitable active substances additionally include:
[0042] Ergolin derivatives such as the lisuride, [3-(9,10-didehydro-6-methyl-8[alpha]-ergolinyl)-1,1-diethylurea], the bromolisuride [=3-(2-bromo-9,10-dehydro-6-methyl-8[alpha]-ergolinyl-1,1-diethylurea], the terguride [=3-(6-methyl-8[alpha]-ergolinyl-1,1-diethylurea], and the proterguride [=3-(6-propyl-8[alpha]-ergolinyl)-1,1-diethylurea].
[0043] Antihypertensive agents such as 7[alpha]-acetylthio-17[alpha]-hydroxy-3-oxo-4-pregnen-21-carboxylic acid-[gamma]-lactone and 7[alpha]-acetylthio-15[beta]-, 16[beta]-methylene-3-oxo-17[alpha]-pregna-1,4-diene-21,17-carbolactone (=mespirenon).
[0044] Anticoagulants such as 5-[hexahydro-5-hydroxy-4-(3-hydroxy-4-methyl-1-octen-6-ynyl)-2(1H)-pentalenylidene)]-pentanoic acid (=iloprost) or (Z)-7-[(1R,2R,3R,5R)-5-chloro-3-hydroxy-2-[(E)-(3R)-3-hydroxy-4,4-dimethyl-1-octenyl]-cyclopentyl]-5-heptenoic acid (=nocloprost).
[0045] Psychopharmaceuticals such as 4-(3-cyclopentyloxy-4-methoxyphenyl-2-pyrrolidone (=rolipram) and 7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one."

Moreover, the applicants' invention as represented by claim 1 is not merely the selection of a specific active ingredient, i.e. lidocaine, but a bioadhesive pharmaceutical dosage form which can be administered nasally and is in film form wherein the lidocaine containing layer has 30% to 60% by weight lidocaine based on the total amount of crosslinked hydrophilic polymers; has a tear strength of 40 N and the hydrophilic polymer of the active ingredient-containing layer has been crosslinked in situ and the ratio of hydrophilic polymers to crosslinker is from 2:1 to 5:1 by weight, i.e. the invention is the presence of all these claimed elements simultaneously, not each element in isolation.

4) "..[a]pplicant's argument concerning the problem of crystallization with drug loading is not found convincing"

As there was not other supporting evidence for this opinion, it is presumed that the opinion was based on a paragraph [0046] of Rupprecht which stated:

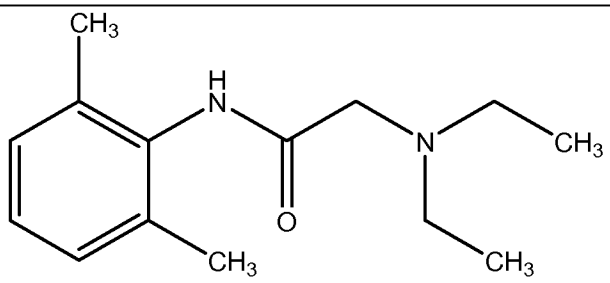
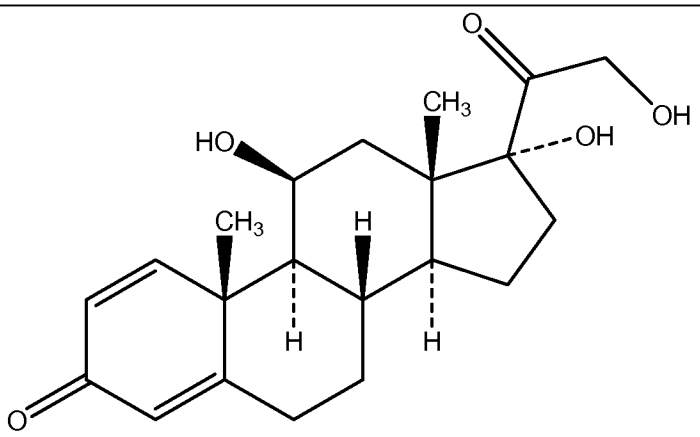
"The multi-layer film according to the invention preferably ***may*** contain up to 30% of ***active substance***, relative to the weight of the film itself, without affecting the mechanical properties of the multi-layer film." (emphasis added).

There are several problems with associating this passage as being a teaching against the applicants' claimed range for lidocaine.

First, this passage is not a positive recitation that the 30% limitation is applicable to all active substances. Given the structural diversity of the potential compounds which could be "active substances" for Rupprecht, one of ordinary skill in the art would not find it surprising that one or more of the active substances cited in paragraphs [0028] – [0045] would fail to achieve the claimed level of content in the dosage form.

The applicants explained in the specification that the state of the art was such that only a 25% loading was expected for lidocaine when using an element of the applicants' claimed invention (use of ethylcellulose) – see paragraph [0011] of the publication of the application. The applicants have surprisingly found that when all of the claimed elements are present in the dosage form, higher levels of loading were possible for lidocaine without crystallization.

With regard to the "as a whole" consideration, this also refers to the fact that what little guidance Rupprecht does give for the amount of lidocaine can only be found in an examples for a compounds of great structural and therapeutic variance, i.e. prednisolone, which is used in an amount which does not even come close to Rupprecht's self-described 30% range.

	
lidocaine	prednisolone

Moreover, there is nothing within Rupprect or Levin which suggests that even if levels of lidocaine of 30% or greater were achieved, that it was achieved without crystallization of the lidocaine as stated in the specification.

As such, there is nothing within Rupprecht alone or in combination with Levin which would suggest that the claimed content of lidocaine was possible for the claimed dosage forms. As there is no other supporting evidence which contradicts the applicants' arguments or

statements made in the specification, the counterargument does not serve to establish that the 30% to 60% range element for the amount of lidocaine was taught or suggested by Rupprecht in combination with Levin.

Lastly, even if the applicants had not objected to any of the counterarguments in the previous Office Action, the applicants hold that the original case of prima facie obviousness was never reestablished.

It is well known that "[w]hen prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker ***must start over***. . . . ***An earlier decision should not***, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then ***be evaluated only on its knockdown ability***. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, ***not against the conclusion itself***. . . . [A] final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record." *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976)(emphasis added).

Reestablishing *prima facie* obviousness still requires a preponderance of evidence, i.e. the totality of evidence must be more likely than not that the claimed invention is obvious. Put another way, the Examiner can still have significant doubts about the obviousness of a claim, but if the totality of the evidence is not a preponderance of the evidence, then no *prima facie* holding has been (re)established.

Given the lack of supporting evidence for the positions taken in the "Response to Arguments", at best the applicants' and Examiner's position were in equipoise, i.e. failed to meet the preponderance of evidence standard necessary for *prima facie* obviousness.

When further viewed in light of the arguments presented above, there is clearly no basis for the obviousness rejection in view of the combination of Rupprecht and Levin.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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